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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/184,043	11/02/1998	HANS HORNAUER	P564-8023	3802

7590 05/31/2002

ARENT FOX KINTNER PLOTKIN & KAHN PLLC
1050 CONNECTICUT AVENUE, N.W.
SUITE 600
WASHINGTON, DC 20036-5339

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/184,043

Applicant(s)

HORNAUER ET AL

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2002 and 28 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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1) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2) Claim 14 is again rejected under 35 USC 112, second paragraph, as being indefinite in the use of the term "test reagent" for the reason stated in paragraph 4.c) of the last Office action. Applicants' mere statement that "test reagents that can be used in the claimed invention are known to those of ordinary skill in the art" does not establish the nature, type and specificity of these moieties nor does it establish exactly what types of "test reagents" are "known" and appropriate for use in the claimed invention.

3) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have provided no indication of where the added limitation which defines the "test reagent" appears in the specification.

5) Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by each of Herron et al ('196), Herron et al ('492), or Reichert et al ('165) for the reasons set forth in paragraph 7. of the last Office action.

Applicants address the Herron et al ('196) and Reichert et al patents with the unsubstantiated statement that "none of...Herron '196 and Reichert teach or suggest the use of derivatized analyte-specific reactants" (Remarks, page 2, last sentence).

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Contrary to applicants' statement, the Herron et al and Reichert et al patents do disclose a solid phase on which a PEG-analyte conjugate is immobilized and the use of this solid phase in an assay for the corresponding specific binding pair member of the analyte. See Herron et al ('196): Example III, col. 16, lines 38-45, wherein activated/modified PEG (e.g. PEG-ED₂) was immobilized on a silica support and wherein the other ED moiety was bound to an aldehyde moiety in an antibody or antibody fragment thus forming a silica-PEG-Ab solid phase which is the same as the solid phase of instant claim 14; Herron et al ('492): col. 4, lines 2-12 wherein a silanized support is coated with PEG derivatized with ethylenediamine groups, these groups are reacted with Fab' capture molecules and this support is further used in a sandwich-type assay; Reichert et al: col. 15, line 63 – col. 16, line 3. In the Remarks of November 28, 2001, page three, applicants make the distinction that a "conjugate" of PEG and analyte-specific solid phase reactant is applied to the solid phase in the instant claims while the prior art applies first PEG and then the solid phase reactant. This distinction is not relevant, however, for the reason that instant claim 14 does not in any way limit the manner in which the PEG and solid phase reactant are "applied" to the solid phase. The claim is inclusive of the case in which the "conjugate" is formed by first attaching PEG to the solid support followed by the attachment of the solid phase reactant to the PEG. Further, even if the claim language had required that the PEG-solid phase reactant conjugate be attached as a unit to the solid phase (product by process limitation), the resulting product would appear to be the same as the product used in the prior art methods (MPEP 2113).

5) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE at (703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

May 31, 2002


Mary E. (Molly) Ceperley
Primary Examiner
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